

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of : Pairet, M. et al ) Art Unit: 1617  
U.S. Appln. No. : To Be Accorded ) Examiner: Mojdeh BAHAR  
Confirmation No. : To Be Accorded  
U.S. Filing Date : 02/11/2004  
Title of Invention : Pharmaceutical Compositions Based On Anticholinergics And  
Corticosteroids  
Attny. Docket No.: 1/1174-1-C1

Mail Stop Patent Application  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

February 11, 2004

**TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents listed herein and on the attached PTO-1449 form and which the Examiner may deem relevant to patentability of the claims of the above-identified application. Copies of the citations listed on the PTO-1449 form are filed in US Application No. 10/086,145, filed on October 19, 2001, Pairet, M. et al (Attorney Docket No. 1/1174).

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. § 1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. § 1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. § 1.113, ii) a notice of allowance under 37 C.F.R. § 1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. § 1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. § 1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

☐ The fee set forth in 37 C.F.R. §1.17(p).

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☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

*Michael P. Morris*

Michael P. Morris  
Attorney for Applicant(s)  
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Date: February 11, 2004

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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**Complete if Known**

Application Number	To Be Accorded
Filing Date	02/11/2004
First Named Inventor	Michel PAIRET
Art Unit	1617
Examiner Name	Mojdeh BAHAR
Attorney Docket Number	1/1174-1-C1

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 5,610,163	03/11/1997	Banholzer, R. et al	
		US- 4,042,700	08/16/1977	Banholzer, R. et al	
		US- 4,608,377	08/26/1986	Banholzer, R. et al	
		US- 4,783,534	11/08/1988	Banholzer, R. et al	
		US- 5,654,314	08/05/1997	Banholzer, R. et al	
		US- 5,770,738	06/23/1998	Banholzer, R. et al	
		US- 5,952,505	09/14/1999	Banholzer, R. et al	
		US- 6,486,321	11/26/2002	Banholzer, R. et al	
		US- 6,506,900	01/14/2003	Banholzer, R. et al	
		US- 2003/0018019	01/23/2003	Meade, C. J. M. et al	
		US- 2002/0137764	09/26/2002	Drechsel, K. et al	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		WO 01/78736 A1	10/25/2001	Glaxo Group Ltd.		
		WO 01/78739 A1	10/25/2001	Glaxo Group Ltd.		
		WO 01/78741 A1	10/25/2001	Glaxo Group Ltd.		
		WO 01/78743 A1	10/25/2001	Glaxo Group Ltd.		
		EP 05040112 A2	05/03/1992	Ciba-Geigy AG		

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First Named Inventor	Michel PAIRET
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Examiner Name	Mojdeh BAHAR
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		US-			
		US-			
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		DE 198 35 346 A1	05/08/1998	BI Pharma KG		

Examiner  
Signature

Date

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Application Number	To Be Accorded
				Filing Date	02/11/2004
				First Named Inventor	Michel PAIRET
				Art Unit	1617
				Examiner Name	Mojdeh BAHAR
				Attorney Docket Number	1/1174-1-C1
Sheet	3	of	3		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		F. MON, et al; Aerosol Therapy in Asthma, Revue Des Maladies Respiratoires, Bd. 6, Nr. 3, 1989 Seiten 189-200 - XP001078722	
		G. BLAZANO, et al, Effectiveness and Acceptability of a Domiciliary Multidrug Inhalation Treatment in Elderly Patients with Chronic Airflow Obstruction: Metered Dose Inhaler Versus Jet Nebulizer, Journal of Aerosol Medicine, Vol. 13, No. 1, 2000, PP 25-33	
		RUTGERS, STEVEN R., et al; Short-term Treatment with Budesonide Does Not Improve Hyperresponsiveness to Adenosine 5- Monophosphate in COPD, American Journal of Respiratory and Critical Care Medicine, Vol. 157, pp 880-887	
		CONSTANT P. van SCHAYCK, et al; Periodic Treatment Regimens with Inhaled Steroids in Asthma or Chronic Obstructive Pulmonary Disease, Journal of American Medical Association, July 12, 1995, Vol. 274, No. 2, pp 161-164	
		DEMETRI PAVIA, et al; Preliminary Data from Phase II Studies with Respimat, a Propellant-Free Soft Mist Inhaler, Journal of Aerosol Medicine, Vol. 12, Supplement 1, 1999 pp S-33-S-39	
		KOICHI NISHIMURA, et al; Additive effect of oxitropium bromide in combination with inhaled corticosteroids in the treatment of elderly patients with chronic asthma, Allergology International (1999) 48: 85-88. Short Communication XP-001070756	
		NISHIMURA, ET AL; "Additive effect of oxitropium bromide in combination with inhaled corticosteroids in the treatment of elderly patients with chronic asthma"; Allergology International, 3/1999, pgs 85-88	
		GENNARO, ET AL; Ed., Remington's Pharmaceutical Sciences, 18th Ed., 1990, Pgs 1694-1699, 1706-1707, 1709	

Examiner Signature		Date Considered	
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